CLAIMS

What is claimed is:

1. A diagnostic test for characterizing a human patient's risk of developing or having cardiovascular disease, comprising:

a) obtaining the levels of myeloperoxidase (MPO) activity, myeloperoxidase (MPO) mass, or both in a bodily sample from the human patient, said bodily sample being blood or a blood derivative; and

b) comparing the levels of myeloperoxidase (MPO) activity, myeloperoxidase (MPO) mass, or both, respectively, in the bodily sample from the human patient with one or two predetermined values,

wherein such comparison provides information for characterizing the human patient's risk of developing or having cardiovascular disease.

2. The diagnostic test of claim 1 wherein the level of myeloperoxidase activity in the human patient's bodily sample is obtained by flow cytometry.

3. The diagnostic test of claim 1 wherein one of said one or two predetermined values is a single normalized value or a range of normalized values and is based on the MPO activity levels in comparable bodily samples from the general population or a select population of human subjects.

4. The diagnostic test of claim 1 wherein one of said one or two predetermined values is a single representative value or a range of representative values and is based on the MPO activity levels in comparable bodily samples from the general population or a select population of human subjects.

5. The diagnostic test of claim 1 wherein one of said one or two predetermined values is a plurality of predetermined MPO activity level ranges that are based on the MPO activity levels in comparable bodily samples from the general population or a select population of human subjects, and

said comparing step comprises determining in which of said plurality of predetermined MPO activity level ranges the human patient's MPO activity level falls.

6. The diagnostic test of claim 1 wherein the bodily sample is one or more blood derivative selected from the group consisting of leukocytes, neutrophils, monocytes, mononuclear lymphocytes, sub-populations of neutrophils, sub-populations of neutrophils, sub-populations of monocytes, and sub-populations of mononuclear lymphocytes.

7. The diagnostic test of claim 1 wherein the levels of myeloperoxidase mass in the human patient's bodily sample is obtained by an immunological technique.

8. The diagnostic test of claim 1 wherein one of said one or two predetermined values is a single normalized value or a range of normalized values and is based upon the MPO mass levels in comparable bodily samples from the general population or a select population of human subjects.

9. The diagnostic test of claim 1 wherein one of said one or two predetermined values is a single representative value or a range of representative values and is based upon the MPO mass levels in comparable bodily samples from the general population or a select population of human subjects.

10. The diagnostic test of claim 1 wherein one of said one or two predetermined values is a plurality of predetermined MPO mass level ranges which are based on the MPO mass levels in comparable bodily samples from the general population or a select population of human subjects, and

said comparing step comprises determining in which of said plurality of predetermined MPO mass level ranges the human patient's MPO mass level falls.

11. A diagnostic test for characterizing a human patient's risk of developing or having cardiovascular disease, comprising:

a) obtaining the levels of one or more select myeloperoxidase-generated oxidation products in a bodily sample from the human patient, wherein said bodily sample is urine, blood or a blood derivative, wherein each of said select myeloperoxidase-generated oxidation product

is selected from the group consisting of nitrotyrosine, dityrosine, methionine sulphoxide and an MPO-generated lipid peroxidation product; and

b) comparing the levels of each of said select myeloperoxidase-generated oxidation product in the bodily sample from the human patient with a predetermined value;

wherein said comparison provides information for characterizing the human patient's risk of developing or having cardiovascular disease.

12. The diagnostic test of claim 11 wherein one of said select myeloperoxidase-generated oxidation product is dityrosine, nitrotyrosine, or methionine sulphoxide.

13. The diagnostic test of claim 11 wherein one of said select myeloperoxidase generated oxidation product is an MPO lipid peroxidation product selected from the group consisting of hydroxy-eicosatetraenoic acids (HETEs); hydroxy-octadecadienoic acids (HODEs), F2Isoprostanes; the glutaric and nonanedioic monoesters of 2-lysoPC (G-PC and ND-PC, respectively); the 9-hydroxy-10-dodecenedioic acid and 5-hydroxy-8-oxo-6-octenedioic acid esters of 2-lysoPC (HDdiA-PC and HOdiA-PC, respectively); the 9-hydroxy-12-oxo-10-dodecenoic acid and 5-hydroxy-8-oxo-6-octenoic acid esters of 2-lysoPC (HODA-PC and HOOA-PC, respectively); the 9-keto-12-oxo-10-dodecenoic acid and 5-keto-8-oxo-6-octenoic acid esters of 2-lysoPC (KODA-PC and KOOA-PC, respectively); the 9-keto-10-dodecendioic acid and 5-keto-6-octendioic acid esters of 2-lysoPC (KDdiA-PC and KOdiA-PC, respectively); the 5-oxovaleric acid and 9-oxononanoic acid esters of 2-lysoPC (OV-PC and ON-PC, respectively); 5-cholesten-5α, 6α-epoxy-3β-ol (cholesterol α-epoxide); 5-cholesten-5β, 6β-epoxy-3β-ol (cholesterol β-epoxide); 5-cholesten-3β,7β-diol (7-OH-cholesterol); 5-cholesten-3β, 25-diol (25-OH cholesterol); 5-cholesten-3β-ol-7β-hydroperoxide (7-OOH cholesterol); and cholestan-3β, 5α, 6β-triol (triol).

14. The diagnostic test of claim 11 wherein the predetermined value is single representative value or a range of representative values and is based upon the levels of said select myeloperoxidase oxidation product in comparable bodily samples from the general population or a select population of human subjects.

15. The diagnostic test of claim 11 wherein the predetermined value is a plurality of predetermined MPO activity level ranges which are based on the based upon the levels of said select myeloperoxidase oxidation product in comparable bodily samples from the general population or a select population of human subjects, and

said comparing step comprises determining in which of said plurality of predetermined select myeloperoxidase-generated oxidation product ranges the human patient's select myeloperoxidase-generated oxidation product level falls.

16. A diagnostic test for characterizing a human patient's risk of developing or having cardiovascular disease, comprising:

a) obtaining the levels of myeloperoxidase activity or myeloperoxidase mass or both in a bodily sample from the human patient, said bodily sample being blood or a blood derivative;

b) obtaining the levels of a select myeloperoxidase-generated oxidation product in a bodily sample from the human patient, wherein said bodily sample is blood, a blood derivative, or urine, wherein said select myeloperoxidase-generated oxidation product is selected from the group consisting of free nitrotyrosine, peptide bound nitrotyrosine, free dityrosine, peptide bound dityrosine, free methionine sulphoxide, peptide bound methionine sulphoxide and an MPO-generated lipid peroxidation product, said bodily sample being blood, a blood derivative, or urine;

c) comparing the levels of myeloperoxidase activity, myeloperoxidase mass, or both, respectively in the bodily sample from the human patient with one or two predetermined values; and

d) comparing the level of said select myeloperoxidase-generated oxidation product in the bodily sample with an additional predetermined value,

wherein the comparisons of step c and step d provide information for characterizing the human patient's risk of developing or having cardiovascular disease.

17. A diagnostic test for evaluating a therapeutic agent for cardiovascular disease in a subject suspected of having or having cardiovascular disease, comprising.

comparing the levels of MPO activity or MPO mass in a bodily sample taken from the subject after treatment with said therapeutic agent with the levels of MPO activity or MPO mass, respectively, in a corresponding bodily sample taken from the subject prior to treatment with said therapeutic agent, wherein said bodily sample is blood or a blood derivative.

18. The diagnostic test of claim 17 further comprising the step of comparing the levels of a second risk predictor in a blood sample taken from the subject after treatment with said therapeutic agent with levels of said second risk factor in a blood sample taken from the subject after treatment, wherein the second risk predictor is selected from the group consisting of LDL, C-reactive protein, total cholesterol, HDL cholesterol, triglycerides, LDL/HDL ratio, Lp(a), Interleukin 6, and homocysteine.

19. A diagnostic test for evaluating a therapeutic agent for cardiovascular disease in a subject suspected of having or having cardiovascular disease., comprising.

comparing the levels of one or more select MPO-generated oxidation products in a bodily sample taken from the subject after treatment with said therapeutic agent with the levels of MPO activity or MPO mass in a corresponding bodily sample taken from the subject prior to treatment with said therapeutic agent, wherein said bodily sample is blood, a blood derivative, or urine, and wherein said select MPO-generated oxidation product is free dityrosine, peptide-bound dityrosine, free nitrotyrosine, or peptide-bound nitrotyrosine, free methionine sulphoxide, peptide-bound methionine sulphoxide, or an MPO-generated lipid peroxidation product.

20. The diagnostic test of claim 19 further comprising the step of comparing the levels of a second risk predictor in the blood sample taken from the subject after treatment with said therapeutic agent with levels of said second risk factor in a corresponding bodily sample taken from the subject after treatment, wherein the second risk predictor is selected from the group consisting of LDL, C-reactive protein, total cholesterol, HDL cholesterol, triglycerides, LDL/HDL ratio, Lp(a), Interleukin 6, and homocysteine.

21. The diagnostic test of claim 19 wherein said lipid peroxidation product is selected from the group consisting of selected from the group consisting HETEs, HODEs, F2Isoprostanes, G-PC, ND-PC, HDdiA-PC, HOdiA-PC, HODA-PC, HOOA-PC, KODA-PC, KOOA-PC, KDdiA-

PC, KOdiA-PC, OV-PC, ON-PC, cholesterol α-epoxide, cholesterol β-epoxide, 7-OH-cholesterol, 25-OH cholesterol, 7-OOH cholesterol, and triol.

22. A kit comprising a package comprising an assay for MPO activity, MPO mass, or a select MPO-generated oxidation product, and a chart comprising a predetermined value for correlating the level of MPO acitivity, MPO mass, or select MPO-generated oxidation product in a bodily sample from the subject with cardiovascular disease.